



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

January 13, 1999

MEMORANDUM

SUBJECT: **Phosmet** (List A Reregistration Case No. 0242/Chemical ID No. 059201). HED Response to 30-Day Error Corrections for the 10/30/98 HED Risk Assessment Barcode No. D252047.

FROM: Christina Swartz, Chemist
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THROUGH: Whang Phang, Ph.D., Branch Senior Scientist
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TO: Kathy Monk/Linda Werrell, PM-52
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Background

The HED Human Health Risk Assessment for the organophosphate active ingredient phosmet was summarized in a memorandum dated 10/30/98 (C. Swartz, DP Barcode No. D236026). Supporting documentation for the risk assessment included the following:

Hazard Identification Committee Report: George Ghali, Ph.D., 12/19/97
Toxicology Chapter of the Reregistration Eligibility Decision Document: William Greear, 1/7/98
The ORE Aspects of the HED Chapter of the RED: Jeff Dawson, 5/12/98
Product and Residue Chemistry Chapters of the HED RED: Christina Swartz, 6/18/98
Anticipated Residues for Chronic Non-Cancer Exposure Assessment: David Hrdy, 7/17/98
Acute/Chronic Dietary Exposure/Risk Analyses for the HED RED: Christina Swartz, 10/9/98

An acute neurotoxicity study has been submitted and is currently under review in HED.

Schering-Plough Comments

In a letter dated 8/20/98, registrant Schering-Plough provided the Agency with a list of corrections to the residue chemistry chapter, which were incorporated into a revised product and residue chemistry chapter dated 11/23/98 (C. Swartz, DP Barcode No. D250029). In a second letter dated 12/11/98, Schering-Plough provided additional comments on the ORE Aspects of the HED Chapter of the RED, and on the HED risk assessment. Some of the comments constituted error corrections, whereas other comments were submitted in advance of the 60-day open comment period, but were not considered to be error corrections. Schering-Plough stated that errors in the ORE chapter were then repeated in the human health risk assessment.

HED Response

The HED response to the error corrections for the ORE chapter is summarized in a memo dated 01/13/99 (J. Dawson, DP Barcode No. D252048). The relevant HED responses to these comments will be incorporated into the revised risk assessment at the conclusion of the 60-day public comment period.

Gowan Comments

In a letter dated 12/14/98, Gowan provided EPA with error corrections for the human health risk assessment. The registrant intends to submit additional comments during the 60-day comment period. The comments related to the occupational and residential exposure assessment are summarized in the J. Dawson memo dated 01/13/99 (DP Barcode No. D252048). Other Gowan corrections are presented herein, with the HED response immediately following, in italics.

Page 2, Background: Due to new instructions sent to Gowan in a letter dated 11/13/98, significant modifications to the Monte Carlo acute dietary exposure and risk assessment were requested. Gowan maintains that the interim guidance described in the 11/13/98 memo may change at the conclusion of the comment period for the draft "Guidance for Submission of Probabilistic Human Health Exposure Assessments to the Office of Pesticide Programs."

Acute dietary exposure and risk for phosmet currently exceed the Agency's level of concern. Submission of a probabilistic exposure analysis is recommended to refine the risk assessment. HED recommends the registrant use best scientific judgement and available information in submitting a probabilistic assessment prior to the end of the 60-day comment period. The probabilistic analysis should be conducted in accordance with the Draft Guidance.

Page 3, Summary/Conclusions: The last sentence reads "...the Agency will conduct and aggregate...." It should be changed to "...the Agency will conduct an aggregate...."

HED concurs.

Page 4, Data Requirements (Toxicology): Gowan contends that a dermal sensitization study [OPPTS Guideline No. 870.2600] was submitted to EPA under MRID No. 40361301; this study was not cited in the 1/7/98 Toxicology Chapter. The study was conducted by the previous phosmet basic registrant.

HED will locate the study and review it during the 60-day comment period and the 90-day period for risk assessment revisions. If the study has already been reviewed, a copy of the review will be provided to SRRD.

Page 4, Data Requirements (Chemistry): Gowan notes that storage stability data for alfalfa forage and almonds [OPPTS Guideline No. 860.1380] have been submitted to the Agency (MRID No. 44673501).

The data are under review in HED and will be included in the HED revised risk assessment following the 60-day comment period.

Future Data: A subchronic (90-day) neurotoxicity study [OPPTS Guideline No. 870.6200] and a 21-day dermal toxicity study [OPPTS Guideline No. 870.3200] will be submitted at the end of January, 1999.

Provided the data are submitted within the 60-day comment period, HED will review the data and incorporate relevant information into a revised risk assessment.

cc: Reviewer, C. Swartz; List A File; SF.
CSwartz:RRB1:CM2:Rm804F:703 305 5877:01/08/99